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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/403,539	10/22/1999	NICHOLAS M. DEAN	ISIS-3013	7420

7590

05/02/2002

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EXAMINER

ZARA, JANE J

ART UNIT PAPER NUMBER

1635

DATE MAILED: 05/02/2002

18

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/403,539

Applicant(s)

DEAN ET AL.

Examiner

Jane Zara

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 February 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 27-29, 33 and 34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 27-29, 33 and 34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

File

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DETAILED ACTION

This Office action is in response to the communication filed February 12, 2002, Paper No. 17.

Claims 27-29, 33, 34 are pending in the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Response to Arguments and Amendments

Withdrawn Rejections

Any rejections not repeated in this Office action are hereby withdrawn.

Maintained Rejections

Claims 27-28, 33, 34 are provisionally rejected under the judicially created doctrine of double patenting for the reasons of record set forth in the Office action mailed August 8, 2001, Paper No. 15.

No arguments have been presented addressing this rejection.

Claims 27-28, 33, 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Simon et al, Arnold, Jr. et al or Agrawal et al in view of Hanecak et al Vlassov et al and Milligan et al for the reasons of record set forth in the Office action mailed August 28, 2001, Paper No. 15.

Applicant's arguments filed February 12, 2002 have been fully considered but they are not persuasive. Applicants assert that the primary references of Arnold, Simon and Agrawal do not

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teach or suggest oligonucleotides comprising a 2'-alkoxyalkoxy modification and furthermore that there was no motivation to combine the modifications claimed, whereby such modified oligonucleotides are administered to the alimentary canal. Contrary to Applicants' assertions, Arnold, Simon and Agrawal teach the incorporation of 2'-O-alkyl modifications into oligonucleotides for enhancing stability, and 2'-O-alkyls include 2'-methoxyethoxy groups. Furthermore, Hanecak et al teach oligonucleotides comprising 2'-O-methoxyethoxy modifications for enhancing stability and target binding. The motivation to incorporate such 2'-O-alkyl modifications into oligonucleotides (i.e. for increasing stability) had been taught routinely in the art at the time the invention was made, as disclosed previously by Arnold, Simon, Agrawal and Hanecak. One of ordinary skill in the art would have expected that the incorporation of 2'-O-methoxyethoxy groups would increase stability of oligonucleotides. One of ordinary skill in the art also would have expected from the teachings of Agrawal and Milligan that the incorporation of MMI into internucleotide linkages increases oligonucleotide stability, cellular uptake and target binding of the oligonucleotides. In addition, Simon teaches the incorporation of 2'-O-alkyl modifications in order to resist oligonucleotide degradation under acidic conditions which are encountered in the alimentary canal. The motivation and means to incorporate both 2'-O-alkyl modifications and internucleotide modifications had been taught by Agrawal and Arnold for enhancing target binding and stability of oligonucleotides. Therefore the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

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Conclusion

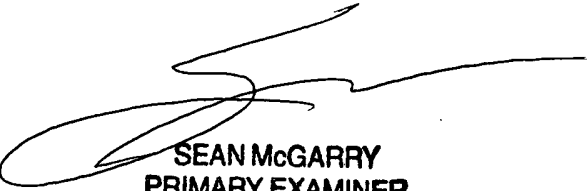
THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Certain papers related to this application may be submitted to Art Unit 1635 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone numbers for the Group are (703) 308-4242 and (703) 305-3014. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jane Zara** whose telephone number is **(703) 306-5820**. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader, can be reached on (703) 308-0447. Any inquiry regarding this application should be directed to the patent analyst, Katrina Turner, whose telephone number is (703) 305-3413. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



SEAN McGARRY
PRIMARY EXAMINER

JZ

April 25, 2002